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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,117	02/27/2002	David W. Morris	PP23697.0001/20366-005001	7176

55255 7590 11/16/2007  
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EXAMINER
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AEDER, SEAN E

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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11/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/085,117

Applicant(s)

MORRIS ET AL.

Examiner

Sean E. Aeder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24,26,27,29 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,26,27,29 and 37 is/are rejected.
- 7) ☒ Claim(s) 24 and 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/27/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

***Detailed Action***

***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 10/18/07 has been entered.

Claim 37 has been newly added.

Claims 24, 26, 27, 29, and 37 are pending.

Claims 24 and 27 have been amended by Applicant.

Claims 24, 26, 27, 29, and 37 are currently under consideration.

The following Office Action contains New Rejections necessitated by Amendments.

***Objection Withdrawn***

The objection to claim 26 is withdrawn.

***Rejections Withdrawn***

All previous rejections are withdrawn.

***New Objections***

Amended claim 24 is objected to because of an apparent typographical error. Claim 24 recites "...with a level of expression the nucleotide sequence...". There appears to be a word missing between "expression" and "the". It is suspected Applicant intended claim 24 to recite: "...with a level of expression of the nucleotide sequence...". Proper correction is required.

Newly added claim 37 is objected to because of an apparent typographical error. Claim 37 recites: "...a polypeptide encoded for by SEQ ID NO:167". The word "for" seems out of place. It is suspected Applicant intended claim 37 to recite: "...a polypeptide encoded ~~for~~ by SEQ ID NO:167". Proper correction is required.

***New Rejections******Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26, 27, 29, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Independent claims 24 and 27 recite methods of diagnosing colon cancer comprising determining levels of a nucleotide sequence comprising SEQ ID NO:167, full complements thereof, and variants thereof wherein a patient sample with a level of expression of the nucleotide sequence that is at least 50% less than the level of expression of the nucleotide sequence in a second sample indicates that the patient has colon cancer. Descriptions of methods of diagnosing colon cancer comprising determining levels of a nucleotide sequence comprising SEQ ID NO:167, full complements thereof, and variants thereof wherein a patient sample with a level of expression of the nucleotide sequence that is at least 50% less than the level of expression of the nucleotide sequence in a second sample indicates that the patient has colon cancer are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. The specification discloses that SEQ ID NO:167 is a cancer associated (CA) nucleic acid (page 10 lines 9-12 and table 1, in particular). The specification further discloses that CA nucleic acids are nucleic acids that were identified through use of oncogenic retroviruses, whose sequences insert into the genome of lymphatic tissue resulting in carcinoma (page 3 lines 17-29 and page 7 lines 20-24, in particular). The specification further discloses that CA nucleic acids can be downregulated in carcinomas *and* discloses that CA nucleic acids can be upregulated in carcinomas (see lines 29-

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38 on page 7, in particular). *However*, of the hundreds of CA nucleic acids disclosed in the specification (see Table 1), the specification does not disclose which CA nucleic acids are upregulated and which are downregulated in particular carcinomas.

Independent claim 24 recites a method comprising determining the level of a nucleotide sequence comprising a sequence at least 98% identical to SEQ ID NO:167, wherein the nucleotide sequence encodes a polypeptide which binds to the promoter of the inosine-5'monophosphate dehydrogenase type II gene.

Descriptions of a method comprising determining the level of a nucleotide sequence comprising a sequence at least 98% identical to SEQ ID NO:167, wherein the nucleotide sequence encodes a polypeptide which binds to the promoter of the inosine-5'monophosphate dehydrogenase type II gene are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. In the submission filed on 10/18/07, Applicant states that it was well known that Egr1 (polypeptide encoded by SEQ ID NO:167) binds to the promoter of the inosine-5'monophosphate dehydrogenase type II gene. However, descriptions of Egr1 binding to the inosine-5'monophosphate dehydrogenase type II gene or descriptions of a genus of variant polypeptides that bind to the inosine-5'monophosphate dehydrogenase type II gene are not disclosed in the instant specification.

Further, dependent claim 37 is drawn to a method comprising determining the level of a nucleotide sequence comprising a sequence at least 98% identical

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to SEQ ID NO:167, wherein the nucleotide sequence encodes a polypeptide which binds to the promoter of the inosine-5'monophosphate dehydrogenase type II gene and has the same cell proliferation activity as a polypeptide encoded by SEQ ID NO:167. Descriptions of a method comprising determining the level of a nucleotide sequence comprising a sequence at least 98% identical to SEQ ID NO:167, wherein the nucleotide sequence encodes a polypeptide which binds to the promoter of the inosine-5'monophosphate dehydrogenase type II gene and has the same cell proliferation activity as a polypeptide encoded by SEQ ID NO:167 are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. In fact, the instant specification provides no guidance as to what kind of proliferation activity a polypeptide encoded by SEQ ID NO:167 would have.

### ***Summary***

No claim is allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'SEA' or similar, written in a cursive style.

SEA